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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/442,284	11/19/1999	RAPHAEL F. MELOUL	MENLO-103-DI	5637

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EXAMINER

GHAFOORIAN, ROZ

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/442,284

Applicant(s)

MELOUL ET AL.

Examiner

Roz Ghafoorian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 38 and 39 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 1999 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claims 21-22 are objected to because of the following informalities: in claim 21 the applicant has recited " a catheter for use in a system for intraluminal treatment of a selected site in a body of a patient by at least one treating element moveable by means of pressurized fluid, the catheter comprising" lines 1-4, since the applicant used the wording "use in" in the first line the following limitations are not considered part of the device and instead are interpreted as intended use, furthermore the description is given in the preamble , if the applicant wishes to argue the moveably of the treatment element via pressurized fluid, he must positively recite it. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 21-22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The applicant recites "... at least one radiopaque marker for aligning said distal end and the at least one treating element with the selected site of the body of the patient, said radiopaque marker being located within the first lumen at said distal end and providing a fluid flow path between said first and second lumen." lines 1-4. However, it is unclear how the radiopaque marker is located in the first lumen and at the same time provide a fluid flow path between the first and second

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lumens, furthermore, the specification shows no support for such a claim. Clarification is required.

3. Claim 21 recites the limitation "the treatment element" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No.5527290 to Zadini et al.

Zadini teaches a catheter having a proximal and distal end usable in a system for intraluminal treatment of a selected site of a patient including a transfer device 16 having a central opening for receiving the catheter and for storing at least one treatment element and propelling the treatment element into a lumen in the catheter comprising a connector integral with the proximal end of the catheter including a detent for securing the connector in the central opening of the transfer device; the detent comprises a cantilever arm axially extending from the connector.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No.6334064 to Fiddian-Green, and further in view of US Patent No.4838881 to Bennett.

Fiddian-Green teach a catheter with an elongated tube having a proximal and distal ends, first and second lumen extending between the proximal and distal ends and communication at the distal ends, the first lumen sized to receive a treatment element. Further comprises a radiopaque marker in the a lumen.

However Fiddian-Green does not teach lumen having an elliptical cross section. Bennett discloses a multilumen catheter comprises separate proximal IV tubes of substantially circular cross-section welded in fluid communication with each of the substantially elliptical-shaped lumens of the catheter.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have combined the two studies. Because as states by Bennett, elliptically shaped lumens essentially eliminate flow problems caused by lumen wall junctures while at the same time using available catheter cross-section area more efficiently than circular-shaped lumens. Whereas a case can be made that

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elliptically shaped lumens are optimal for the design of a multilumen catheter. (Col.2, lines 26-30)

6. Claim 38-39 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5899882 to Waksman, and further in view of Rossemann et al U.S Patent No. 5395332.

Waksman discloses an apparatus and method for delivery of a treating element, such as a radiation source, with multilumen catheter. Waksman, however, does not teach the use of high density/low density polyethylene on the lining of the lumen. Rossemann discloses a catheter for use in angioplasty, which does utilize density polyethylene.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have a blend of high and low polyethylene lining because applicant has not disclosed that the blend provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with high density polyethylene lining because both linings perform the same function.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have combined the studies, because according to Rossemann Polyethylene is a relatively lubricous, flexible and high strength material. (Col.8, line 8-11)

Response to Arguments

7. Applicant's arguments with respect to claims 19-20, 21-22 and 38-39 have been considered but are moot in view of the new ground(s) of rejection.

a. Applicant's arguments with respect to claims 19-22 have been considered but are moot in view of the new ground(s) of rejection.

b. Regarding claim 21 the applicant has argued the prior art does not teach a treating element moveable by means of pressurized fluid, however the applicant used the wording "use in" before reciting the moveably of the treating elements via pressurized fluid in the first line hence limitations are not considered part of the device and instead are interpreted as intended use, furthermore the description is given in the preamble, if the applicant wishes to argue the moveably of the treatment element via pressurized fluid, he must positively recite the limitations.

c. Regarding claim 22, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., for aligning the distal end and the at least one treating element with the selected site of the body of a patient) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

d. Regarding claims 38-39, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. a lining that resists damage from the guidewire) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Although the applicant has only claimed the resists to damage via intend use the lining in the prior art still meet the limitation because the lining in Rossemann is used for lubrication, and lubrication is most often used to resist against damage. Furthermore the applicant claims the lining to be a blend of high and low polyethylene, however gives no reason or evidence in the specification (pages 36-37) why it would be beneficial to use a blend of high and low polyethylene.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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RG

March 7, 2003

A handwritten signature in black ink, appearing to be 'R. J. Hayes'.A handwritten signature in black ink that reads 'Michael J. Hayes'.

MICHAEL J. HAYES
PRIMARY EXAMINER